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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,597	06/12/2008	Janet Shipley	MWB-0004	9071

77845 7590 08/05/2009

Goodwin Procter LLP
Attn: Patent Administrator
135 Commonwealth Drive
Menlo Park, CA 94025-1105

EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
08/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,597	SHIPLEY ET AL.	
	Examiner	Art Unit	
	J. E. Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *17 and 20-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *4-16,18 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

This Action is in response to the communication filed on 4/10/2009.

Claims 1-41 are currently pending.

Election/Restrictions

1. Applicant's election with traverse of Group I as well as antisense RNA and breast cancer (i.e., claims 1-16, 18, 19) in the reply filed on 4/10/2009 is acknowledged. The traversal is on the ground(s) that the present application provides the first hard evidence of a functional link between GPC5 and cancer cell proliferation. This is not found persuasive because Groups I-III are clearly different methods, that is, Groups I-III clearly represent different categories of invention. Applicants contend that all three groups should be rejoined because the evidence presented in the application provide a special technical feature that links all claims. However, it is respectfully pointed out that the inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

In the instant case, Groups I-III represent different categories of invention where each category is a different process. 37 CFR 1.475(b) sets forth the 5 specific combinations of categories of invention which can have unity of invention, none of which are include multiple uses. Therefore, the methods of Groups I-III do not have unity of invention, regardless of the teaching of Yu, et al.

With respect to the types of antagonists, it is respectfully pointed out that each of the antagonists the claims encompass nucleotide as well as non-nucleotide agents. Clearly nucleotide and non-nucleotide agents do not share a common structural feature. With respect to the nucleotide agents (i.e., antisense RNA, double stranded RNAi/siRNA, ribozyme), it is noted that antisense RNAs, double stranded RNAs and ribozymes do not share a substantial structural feature essential to their utility because (1) they are structurally distinct molecules as antisense RNAs are single stranded while double stranded RNAs are double stranded, (2) ribozymes have complex secondary structures while antisense and dsRNAs do not. Furthermore, each of the nucleotide antagonists utilize different biological pathways. For instance, ribozymes are catalytic RNAs while antisense and dsRNAs are not. Double stranded RNAs utilize the enzyme RISC while ribozymes and antisense RNAs do not. Antisense RNAs bind with complementary mRNAs and physically obstructing translation. MPEP 803.02 indicates: "Broadly, unity of invention exists where compounds included within a Markush group (1)share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, for at least the reasons indicates above, antisense RNAs, dsRNAs and ribozymes do not have unity of invention. Therefore, Applicants arguments are not persuasive.

2. Claims 17, 20-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/10/2009.

3. Claims 1-16, 18 and 19 are under consideration.

Specification – Sequence Compliance

4. The disclosure is objected. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, pages 38-40 of the specification contain sequences which require sequence identifiers (i.e., SEQ ID NO) but none are provided. It is assumed that the indicated sequences also do not appear in the Paper Sequence and CRF, as required. Appropriate correction is required. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Applicant is requested to return a copy of the attached Notice to Comply with the response.

Claim Objections

5. Claims 4-16, 18 and 19 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. The instant claims are drawn to a method of inhibiting the proliferation of a target cell by contacting the cell with a GPC5 antagonist or a GPC5 binding agent. As such, the claims encompass using any GPC5 antagonist or GPC5 binding agent. Thus, the claims encompass a genus of different GPC5 antagonists and GPC5 binding agents where each member of the genus would have a common function of inhibiting proliferation; however, the genus encompasses a myriad of structurally distinct molecules related only by their common function of being GPC5 antagonists or GPC5 binding agents that inhibit cell proliferation.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is that the molecules share a common function: GPC5 antagonist or GPC5 binding agents that inhibit cellular proliferation. There is no requirement that the molecules have any structural relationship. In fact, there is not even an identification of any particular portion of the structure that must be conserved. Furthermore, the claims encompass a vast number of structurally distinct molecules including nucleotide based molecules such as antisense RNAs, dsRNAs, ribozymes,

as well as polypeptide based molecules such as antibodies, polypeptide antagonists, and other non-nucleotide, non peptide agents such as small molecule inhibitors. Therefore, a skilled artisan cannot envision the detailed chemical structure of the genus of molecules encompassed by the claims. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Regarding the claimed genus of molecules, the specification has only provided an adequate description of the nucleotide sequence that is complementary to the sequence of the GPC5 mRNA or pre-mRNA and that inhibit the expression of GPC5 that meet the provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the

written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635

UNITED STATES PATENT AND TRADEMARK OFFICE

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UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 20231
www.uspto.gov

APPLICATION NO./CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR /PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER
J. Eric Angell

ART UNIT	PAPER
1635	

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R.. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the one month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **[your name]** whose telephone number is **(703)-XXX-XXXX.**